
Urgent Field Safety Notice

DGDE DirectGuide™ Drill Extender
FSCA-identifier: FSCA-ID2015-11-03 – (pending)
Type of action: Device Exchange

Date: November 3, 2015

Attention: Valued customer(s)

Name:

Address:

Telephone:

Order Number:

Details on affected devices:

Implant Direct Sybron Manufacturing LLC is recalling 25 lots(s) of the DGDE DirectGuide™ Drill Extender (DGDE).

Product Description	Part Numbers	Lot Number
DGDE– DirectGuide™ Drill Extender	DGDE, SPCST, IBST, BST, CST, ICST, IBST, RBST, RCST	61928, 64895, 64898, 64896, 65406, 65405, 65407, 65408, 65410, 65409, 65357, 67055, 67475, 67345, 67476, 67474, 67478, 67477, 67479, 67527, 68254, 68266, 68253, 68265, 68262,

Description of the problem:

Through our internal Regulatory Affairs evaluation (HHE) process we have found a possible safety issue with the retention of the drill when the DGDE is in use. This discrepancy may lead to the possibility of the DGDE dropping the drill. Our current data indicates the possibility of this occurring is unlikely (0.69%). In the unlikely event the DGDE drops the drill; there is a risk if the product is in use that the drill can possibly fall onto the patient, or into the patient's oral cavity. This may lead for the need of additional patient care.

There have been no reported illnesses, injuries, or death regarding this issue.

Advise on action to be taken by the user:

- *Identifying and quarantining the device,*
- *COMPLETE AND RETURN Acknowledgement and Recall Return Form*
- *Inform Implant Direct Sybron Manufacturing LLC of any adverse event immediately*
- *Return any of the described products for product exchange using the provided return label.*

Contact reference person:

Stephanie Bergeron
Implant Direct Sybron Manufacturing LLC
3050 E. Hillcrest Drive
Thousand Oaks, CA 91362
Phone: 818-444-3393

Return and Contact person:

Hans Scheepens
Implant Direct Europe AG
Hardturmstrasse 161 8005 Zurich, Switzerland
Phone: 41 44 567 8100

The undersigned confirms that this notice has been sent to the appropriate Regulatory Agency.

Implant Direct Sybron Manufacturing LLC maintains its commitment in providing customers with high quality and high value dental products. We apologize for any inconvenience this Field Safety Corrective Action may cause and we greatly appreciate your cooperation.

Stephanie Bergeron
RA Supervisor

DGDE-DirectGuide™ Drill Extender

Acknowledgement and Recall Return Form

Product Description	Part Numbers	Lot Number
DGDE– DirectGuide™ Drill Extender	DGDE	

- We acknowledge receipt of the DGDE– DirectGuide™ Drill Extender Recall Notification. We have checked our inventory and were able to locate one or more units of the above-mentioned product. We will be returning the following quantity to Implant Direct Sybron Manufacturing.***

Authorized Implant Direct Sybron Manufacturing LLC Distributors: Additionally, we acknowledge that we will identify those customers that may have been shipped the affected product lot and contact these customers within forty-eight (48) hours of receipt of this notification in order to recover their affected product.

Quantity Returned

- We acknowledge receipt of the DGDE– DirectGuide™ Drill Extender Recall Notification. We have checked our inventory and were unable to locate any of the above-mentioned product.***

Authorized Implant Direct Sybron Manufacturing LLC Distributors: Additionally, we acknowledge that we will identify those customers that may have been shipped the affected product lot and contact these customers within forty-eight (48) hours of receipt of this notification in order to recover their affected product.

Contact Person (Please Print)

Facility

Signature

Date

***WE ALSO KINDLY REQUEST YOUR COOPERATION IN
FAXING/EMAILING/MAILING (RETURN LABEL INCLUDED) THIS
ACKNOWLEDGEMENT FORM TO THE FOLLOWING
NUMBER/EMAIL ADDRESS TO CONFIRM YOUR RECEIPT OF THIS
NOTIFICATION WHETHER OR NOT YOU HAVE ANY AFFECTED
PRODUCT.***

888-649-6425/customer.claims@implantdirect.com